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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/725,282 | 12/01/2003 | Courtney Flem Morgan | CL/V-32784A | 1827 |
| 31781 | 7590 | 09/14/2005 | EXAMINER | |
| CIBA VISION CORPORATION PATENT DEPARTMENT 11460 JOHNS CREEK PARKWAY DULUTH, GA 30097-1556 | | | COLLINS, DARRYL J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 2873 | |

DATE MAILED: 09/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/725,282 | Applicant(s) MORGAN ET AL. | |
| | Examiner Darryl J. Collins | Art Unit 2873 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-10, 12, 13, 15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10, 12, 13, 15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,7,9 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the Remarks mailed August 2, 2005, the Applicant's representative has argued that support for the added "centered optical zone" limitation appears in the first paragraph on page 4 and on the first paragraph bridging pages 5 and 6 of the Specification. The first paragraph on page 4 (repeated below) –

"In sum, the present invention can alter the location of the optical zone(s) on the contact lens carrier such that the zone(s) can be optimized relative to the true line of sight either by decentering the optical zone(s) on the lens based upon the results of the lens movement equilibrium and steady-state positions, or through adjusting the mechanical features of the lens to permit centered optics to be carried in the optimum location by the contact lens. The present invention accordingly provides an advantage in that the inventive contact lens and method of manufacture can utilize the unique measurements of the individual eye of the wearer to align the one or more optical zones of the contact lens with the true line of sight of the eye of the wearer, and not assume simple alignment of the line of sight with the geometric or mechanical access. The precision of location of optical zone(s) thus gives a wearer having a non-geometrically centered line of sight a modification of vision superior to that of a prior art geometric line of sight contact lens."

teaches a mechanical feature to permit the centered optical zone to be carried in the optimum location by the contact lens. In the first paragraph bridging pages 5 and 6 (repeated below) –

“To maintain the contact lens 20 in the optimal position for the optical zone 22 to remain substantially in line with true line of sight B, the contact lens 20 can include mechanical features known in the art to keep the contact lens positionally maintained, such as ridges, ballast, and slab-offs. Further, the optimal placement of the one or more optical zones 22 and 24 can be determined from clinical analysis of the eye 30 of the wearer such as corneal topography and wavefront analysis. Such clinical measurement data is typically provided by the clinician to the manufacturer of the contact lens. And the placement of one or more optimal optical zones 22 and 24 of the contact lens 20 can be adjusted based upon use in the eye 30 of the wearer and iteration of the measurement and fitting process.”

a reference to a “centered optical zone” fails to appear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payor et al in view of Tanaka et al. Payor et al teaches a contact lens (Figure 10, element 80) having one or more optimized optical zones that accommodate the specific optical variations of the wearer's eye (Figure 10, elements 82 and 84) wherein one or more optical zones are placed within the contact lens in relation to the line of sight of the wearer (column 7, lines 41-47), but fails to teach the placement of the optical zones being determined from the relative measurements of a test lens and the center of the cornea as claimed in independent claim 1. Payor et al also teaches mechanical features such that the optical zone or zones are positionally maintained while being worn by the wearer (column 5, lines 61-65) as claimed in dependent claim 2 and the placement

of the optical zones based upon the use in the eye of the user (column 7, lines 41-57) as claimed in dependent claim 5. However, Tanaka et al does teach a contact lens having multiple optical zones (Figure 1, elements 2 and 4) wherein the contact lens is tailored to the particular eye characteristics of the lens wearer via a offset measurement of the test contact with respect to the center of the eye pupil (column 6, lines 33-60) as claimed in independent claim 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the well-known contact optimization techniques as taught by Tanaka et al with the well-known contact lens of Payor et al to achieve a contact lens tailored to the contact lens wearer.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Payor et al in view of Tanaka et al as applied to claims 1, 2 and 5 above, and further in view of Lieberman. Although Payor et al and Tanaka et al teach or fairly suggest all limitations as claimed in independent claim 1, Payor et al and Tanaka et al fail to teach the use of corneal topography as a technique in the design of the contact lens. Lieberman et al teaches the use of corneal topography as a well-known technique in the design process of a multiple zoned contact lens (column 2, lines 45-49) as claimed in dependent claim 3. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the technique as taught by Lieberman et al to construct the contact lens as taught by Payor et al and Tanaka et al to provide a better fit for the contact wearer.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Payor et al in view of Tanaka et al as applied to claims 1, 2 and 5 above, and further in view of Glady et al. Although Payor et al and Tanaka et al teach or fairly suggest all limitations as claimed in independent claim 1, Payor et al and Tanaka et al fail to teach the use of a multi-axis cutting

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system for creating the claimed contact lens. Gladys et al teaches the use of the well-known process of using a multi-axis lathe (column 7, lines 40-48) in the contact lens manufacturing art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the well-known technique of contact lens manufacturing as taught by Gladys et al to achieve the multiple zones contact lens as taught by Payor et al and Tanaka et al to achieve a correctly shaped lens.

Claims 7, 9, 10, 12, 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blum et al in view of Tanaka et al. Blum et al teaches a method of manufacturing a contact lens having one or more optical zones comprising the steps of obtaining information about the line of sight of the eye (column 2, lines 42-44) and determining the position of the optical zones (column 3, lines 16-30) as claimed in independent claims 7 and 13 and dependent claim 12, but fails to but fails to teach a step wherein the relative measurement of a test lens and the center of the cornea is obtained as claimed in independent claims 7 and 13. Blum et al also teaches a method providing mechanical features to maintain the position of the optical zones with respect to the wearer and to optimize optical zone location (column 3, lines 38-42) as claimed in dependent claim 9 and obtaining information about the line of sight through corneal topography (column 3, lines 21-24) as claimed in dependent claims 10 and 17. Tanaka et al does teach a contact lens having multiple optical zones (Figure 1, elements 2 and 4) wherein the contact lens is tailored to the particular eye characteristics of the lens wearer via a offset measurement of the test contact with respect to the center of the eye pupil (column 6, lines 33-60) as claimed in independent claim 7. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the well-known contact optimization techniques as taught

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by Tanaka et al with the well-known method of manufacturing contact lenses of Blum et al to achieve a method of providing a well crafted contact lens.

Claims 8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blum et al in view of Tanaka et al as applied to independent claim 7 above, in view of Glady et al.

Although Blum et al and Tanaka et al teach or fairly suggest all limitations as claimed in independent claim 7, including the use of a machining technique to produce the contact lens (Blum et al, column 3, lines 43-46), Blum et al and Tanaka et al fail to teach the use of a multi-axis cutting system for creating the claimed contact lens. Glady et al teaches the use of the well-known process of using a multi-axis lathe (column 7, lines 40-48) in the contact lens manufacturing art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the well-known technique of contact lens manufacturing as taught by Glady et al in the manufacture of a multiple zones contact lens as taught by Blum et al and Tanaka et al to achieve a correctly shaped lens.

It should also be noted that by the Applicant's own admission, the mechanical features, as claimed in the instant invention, are well known in the art (first paragraph bridging pages 5 and 6 "mechanical features known in the art to keep the contact lens positionally maintained, such as ridges, ballast, and slab-offs")

Response to Arguments

Applicant's arguments filed August 2, 2005 have been fully considered but they are not persuasive. The Applicant's representative has amended the claims including limitations that are not supported by the Specification as outlined above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl J. Collins whose telephone number is 571-272-2325. The examiner can normally be reached on 6:30 - 5:00 Monday - Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Y. Epps can be reached on 571-272-2328. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



djc



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Primary Examiner